

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

The present invention relates to surgical sponges used for the removal of blood from an operative site and, more particularly, to a biodegradable surgical sponge.

### 2. Prior Art

The unintentional implantation of a surgical sponge in an operative site within a patient is a common problem. Although it is the current practice for a surgical nurse to reconcile the sponge count before wound closure, inadvertent errors occur and a sponge may be left within a surgical site when the wound is closed. When the error is discovered, the surgeon must reexpose the surgical site and retrieve the sponge, causing undue further stress and trauma to the patient.

Surprisingly, although biodegradable materials have enjoyed use in wound dressings (i.e., an application wherein there is no danger of accidental implantation of a foreign body within a patient), the bioabsorbable materials and technology has not been extended for use in pledgets that are used for the intraoperative absorption of blood within the surgical site. There is, therefore, a current need for a surgical sponge that is biodegradable by enzymatic action within the body and wherein the biodegradation products are either absorbed or excreted by the body without harm to the patient.

## SUMMARY

1           It is an object of the present invention to provide a disposable,  
2 bioabsorbable surgical sponge operable for absorbing blood from within a surgical  
3 wound.

4           The features of the invention believed to be novel are set forth with  
5 particularity in the appended claims. However the invention itself, both as to  
6 organization and method of operation, together with further objects and  
7 advantages thereof may be best understood by reference to the following  
8 description taken in conjunction with the accompanying drawings.

#### 9 10                                   **BRIEF DESCRIPTION OF THE DRAWINGS**

11           Figure 1 is an elevational view of a preferred embodiment of a  
12 bioabsorbable surgical sponge in accordance with the present invention.

13           Figure 2 is a cross-sectional view of a surgical sponge in accordance with  
14 the preferred embodiment of the present invention illustrated in Figure 1.

15           Figure 3 is an enlarged view of a portion of the surgical sponge of Figure 2  
16 showing the pores formed between the network of bioabsorbable polymer  
17 filaments.

#### 18                                   **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

19           With reference now to Figures 1-3, a bioabsorbable surgical sponge is  
20 shown in perspective view at numeral 10 in Figures 1 and in cross-sectional view  
21 in Figure 2. An enlarged portion of a filamentous embodiment of the surgical  
22 sponge 10 is shown in Figure 3. The sponge 10, though shown in the shape of a

1 circular pad, may be formed in any desired and sensible shape. The sponge 10 is  
2 comprised of a bioabsorbable material formed into a body having a plurality of  
3 interconnecting pores 30 (Figure 3) that open to the surface of the sponge. The  
4 bioabsorbable material may be a fibrous mass of bioabsorbable filaments 31 or it  
5 may be a bioabsorbable "open cell" foam body.

6 The biodegradable material used for the construction of the sponge should  
7 preferably have a hydrophilic outer surface to facilitate the absorption of blood  
8 into the sponge. Suitable biodegradable materials for fabricating the surgical  
9 sponge 10 include filaments or foam bodies comprised of polymers or copolymers  
10 of lactide, glycolide, caprolactone, polydioxanone, trimethylene carbonate,  
11 polyorthoesters and polyethylene oxide, collagen and high molecular weight  
12 polysaccharides from connective tissue such as chondroitin salts. Other  
13 polysaccharides that can be formed into a porous body may also prove suitable,  
14 such as chitin and chitosan. Additional bioabsorbable materials are in intense  
15 development and it is expected that many of the new materials will also be  
16 applicable for forming a biodegradable surgical sponge in accordance with the  
17 present invention.

18 A filamentous surgical sponge in accordance with the present invention  
19 may be fabricated by weaving the bioabsorbable polymer filaments into a sheet  
20 and cutting appropriately dimensioned pledgets therefrom. Alternatively, a bolus  
21 of filament can be placed into a cylinder heated to a temperature less than, but  
22 close to, the transition temperature of the polymer and compressed with a heated

1 piston to form a circular pad as shown in Figures 1 and 2. The pressure applied to  
2 the piston can be varied to affect the appropriate pad thickness and desired  
3 average pore size. The sponge may be sterilized by heat, ethylene oxide or  
4 radiation, the choice depending on the bioabsorbable material selected.

5 The advantage of a surgical sponge in accordance with the present  
6 invention is that in the event that the sponge is accidentally implanted within the  
7 body when a surgical wound is closed, the sponge will be biodegraded and the  
8 biodegradation products excreted from the body without the need for surgical  
9 explantation. The bioabsorbable surgical sponge reduces surgical complications  
10 due to foreign body response and obviates the need for further surgery thereby  
11 reducing trauma to a patient.

12 While particular embodiments of the present invention have been  
13 illustrated and described, it would be obvious to those skilled in the art that  
14 various other changes and modifications can be made without departing from the  
15 spirit and scope of the invention. It is therefore intended to cover in the appended  
16 claims all such changes and modifications that are within the scope of this  
17 invention.

18 What I claim is: